

**Remarks/Arguments:**

**I. Status**

The Office Action dated September 30, 2009 (the “Office Action”), has been carefully reviewed. Claims 24, 26, 28, and 30 have been amended and claims 33-36 have been added. Accordingly, claims 17-36 are pending in this application and claims 17-23 are withdrawn from examination. Reconsideration of this application is respectfully requested.

**II. Claim Objections**

The Examiner objected to claims 26 and 30 for being directed to a method and not to a system. Claims 26 and 30 have been amended such that the claims are directed to systems. Accordingly, it is respectfully submitted that the objections to claims 26 and 30 have been overcome.

**III. 35 U.S.C. § 102 Rejections**

Claim 24 was rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,721,104 to Kaufman et al. (hereinafter “Kaufman”) and claims 24, 28, and 32 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,976,147 to LaSalle et al. (hereinafter “LaSalle”). Reconsideration of these claims in view of the following remarks is respectfully requested.

*Discussion Re: Patentability of Claim 24 over Kaufman*

1. Claim 24

Claim 24, as amended, recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:  
an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;  
an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and  
a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument, the system configured such that when the femoral resection guide is mated to the connector member and the system is positioned on a tibia, the femoral resection guide is positioned farther away from the tibia when the augment is fixed to the positioning member, than when the augment is not fixed to the positioning member.

Claim 24 thus clarifies that the system components are arranged such that the gap between a tibia and a femur is increased by moving the femoral resection guide away from the tibia when the augment is incorporated.

2. Kaufman Does Not Disclose the Arrangement of Claim 24

The Examiner alleged that Kaufman disclosed the system of claim 24 with reference to components depicted in FIG. 1 of Kaufman. (Office Action at page 2). Claim 24 has been amended to more specifically recite the manner in which the claimed elements are arranged.

Specifically, the Examiner has proposed interpreting the femoral trial 5 to be an augment and the metal portion 60 of the drill guide 2 to be a femoral resection guide. As is evident from FIG. 1, when the femoral component 5 is incorporated into the system, the drill guide 2 is moved upwardly (as depicted in FIG. 1 of Kaufman), and thus closer to the tibia. By fixing the augment of claim 24 to the instrument of claim 24 in the arrangement recited in claim 24, however, the femoral resection guide of claim 24 is

repositioned to a location farther removed from the tibia when the system of claim 24 is placed on a tibia.

An arrangement of components which positions a “femoral resection guide” closer to the tibia as disclosed in Kaufman is not the same as an arrangement of components that positions a femoral resection guide farther away from the tibia as recited in claim 24.

The Federal Circuit has stated:

Because the Hallmark of anticipation is prior invention, the prior art reference --in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”

*Net Moneyin, Inc. v. Verisign, Inc.*, 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Because the “augment” of Kaufman does not position the guide component of Kaufman farther away from a tibia, Kaufman does not disclose an arrangement of components as recited in claim 24. Therefore, Kaufman does not anticipate claim 24.

3. A Femoral Trial is Not an Augment

Moreover, the Examiner has identified the femoral trial 5 of Kaufman as an augment. (Office Action at page 2). A femoral trial is not an augment.

Specifically, the Applicants’ specification at page 9, lines 1-3 states “While the positioner 50 may be properly sized to achieve these results for some patients, the majority of the cases will require some augmentation for the surface alignment plate.” Accordingly, an “augment”, as that term is used in the specification, is a component which may or may not be needed for proper functioning of the system, depending upon the particular case. Kaufman, however, does not identify the femoral trial 5 as an

optional component when using the guide 2. A component which is always required for a system to function properly is not the same as a component that may or may not be needed for a system to function properly for a particular patient. Therefore, the femoral trial of Kaufman is not an augment.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Kaufman does not disclose each and every element of Applicant's claim 24, Kaufman does not anticipate claim 24.

4. Conclusion

For any or all of the foregoing reasons, it is respectfully submitted that the rejection of claim 24 as being anticipated by Kaufman has been successfully traversed, and the Applicants respectfully submit that the rejection of claim 24 under 35 U.S.C. § 102 should be withdrawn.

*Discussion Re: Patentability of Claim 24 over LaSalle*

1. Claim 24

As noted above, claim 24 has been amended to clarify that the claimed system is arranged such that the augment increases the gap between a tibia and a femur by moving the femoral resection guide away from the tibia.

2. LaSalle Does Not Disclose the Arrangement of Claim 24

The Examiner alleged that LaSalle disclosed the system of claim 24 with reference to components depicted in FIG. 1 of LaSalle. (Office Action at page 3). Claim

24 has been amended to more specifically recite the manner in which the claimed elements are arranged.

Specifically, the Examiner has proposed interpreting the tibial bearing insert 20 of LaSalle to be an augment and the trial tibial tray 12 to be a resection guide. (Office Action at page 3). As is evident from FIG. 1, when the tibial bearing insert 20 is incorporated into the system of LaSalle, the location of the trial tibial tray 12 on the tibia 21 (see FIG. 2 of Kaufman) is not affected. As discussed above, by fixing the augment of claim 24 to the instrument of claim 24, the femoral resection guide is repositioned to a location farther removed from the tibia when the system of claim 24 is placed on a tibia.

An arrangement of components which has no effect on the location of a “femoral resection guide” with respect to a tibia as disclosed in LaSalle is not the same as an arrangement of components that positions a femoral resection guide farther away from the tibia as recited in claim 24.

The Federal Circuit has stated:

Because the Hallmark of anticipation is prior invention, the prior art reference --in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”

*Net Moneyin, Inc. v. Verisign, Inc.*, 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Because the “augment” of LaSalle does not position the trial tibial tray of LaSalle farther away from a tibia, LaSalle does not disclose an arrangement of components as recited in claim 24. Therefore, LaSalle does not anticipate claim 24.

3. A Trial Tibial Tray is Not a Femoral Resection Guide

Moreover, the Examiner has identified the trial tibial tray 12 of LaSalle as a femoral resection guide. (Office Action at page 2). A trial tibial tray 12 is not a femoral resection guide.

Specifically, the Applicants' specification at page 3, lines 2-8 states:

Since the femoral component of the knee prosthesis requires complex cuts in the femur, a femoral resection guide is used, such as the resection guide 20 shown in FIG. 2. The main body 22 of the guide 20 is aligned at the distal end of the femur F and held in place by one or more guide pins 24. The resection guide 20 may include other structure and components for maintaining the guide in a proper orientation as the femur is resected.

Thus, the Applicants' specification uses the term "femoral resection guide" to identify a specialized guide for making specific cuts in a femoral component during a knee replacement procedure. In contrast, the trial tibial tray 12 includes a "guide aperture" 30 which is used to "lock other components within the guide aperture 30." (LaSalle at column 4, lines 25-28). The tibial trial tray 12 is thus used to form a hole in the tibia (see LaSalle at column 6, lines 14-18). Forming a hole in a tibia is not the same as resecting a femur to receive a prosthesis. Thus, contrary to the Examiner's allegation, the trial tibial tray of LaSalle is not a femoral resection guide.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since LaSalle does not disclose each and every element of Applicant's claim 24, LaSalle does not anticipate claim 24.

4. Conclusion

For any or all of the foregoing reasons, it is respectfully submitted that the rejection of claim 24 as being anticipated by LaSalle has been successfully traversed, and

the Applicants respectfully submit that the rejection of claim 24 under 35 U.S.C. § 102 should be withdrawn.

*Discussion Re: Patentability of Claim 28 over LaSalle*

1. Claim 28

Claim 28 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:  
an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;  
an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and  
an intramedullary pin received within said guide slot of said positioning member of said instrument.

Claim 28 thus recites a system with a positioning member that includes both a coupler and a slot.

2. LaSalle Does Not Disclose A Positioning Member as Claimed

The Examiner has alleged that LaSalle discloses the system of claim 28 with reference to components depicted in FIG. 1 of Kaufman. (Office Action at page 3). LaSalle does not disclose a positioning member with the characteristics recited in claim 28.

Specifically, the Examiner has proposed interpreting the trial tibial tray 12 and the tibial punch 18 to be an instrument. (Office Action at page 3). The Examiner further identifies the connecting element 90 (see FIG. 6) as a “first coupler.” (Office Action at page 3). The tibial punch 18, however, does not include a “guide slot.” In fact, the Examiner has not even alleged that the tibial punch 18 has a slot. Rather, the Examiner has alleged the shoulder 58 within the trial tibial tray 12 to be a guide slot. The claim

recites, however, that the “first coupler” and the “guide slot” are *both* defined by the positioning member. A tibial punch *without* a guide slot is not the same as a positioning member *with* a guide slot.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since LaSalle does not disclose each and every element of Applicant’s claim 28, LaSalle does not anticipate claim 28.

3. Conclusion

For any or all of the foregoing reasons, it is respectfully submitted that the rejection of claim 28 as being anticipated by LaSalle has been successfully traversed, and the Applicants respectfully submit that the rejection of claim 28 under 35 U.S.C. § 102 should be withdrawn.

*Discussion Re: Patentability of Claim 32*

Claim 32 depends from claim 28 and includes all of the limitations of claim 28 and additional limitations. Therefore, for at least the same reasons set forth above with respect to claim 28, LaSalle does not anticipate claim 32.

**IV. 35 U.S.C. § 103 Rejections**

Claims 25-27, and 29-31 have been rejected under 35 U.S.C. § 103 as being unpatentable over either Kaufman, LaSalle, or a combination of Kaufman or LaSalle with U.S. Patent No. 5,931,838 to Vito (hereinafter “Vito”). Each of claims 25-27 and 29-31 depend, either directly or by way of one or more intermediate claims, from claim 24 or claim 28. The Examiner rejected claims 25-27 and 29-31 based primarily upon Kaufman



or LaSalle with further reference to Vito or some other argument for the limitations recited in claims 25-27 and 29-31. Accordingly, even if Kaufman and LaSalle are modified in the manner proposed by the Examiner, such modification fails to correct the deficiencies of Kaufman and LaSalle with respect to the limitations of claims 24 and 28 as discussed above. Therefore, the proposed modifications fail to arrive at the invention of claims 25-27 or 29-31.

Consequently, for at least the reasons set forth above with respect to claims 24 and 28, claims 25-27 and 29-31 are patentable over the cited art.

**V. Claims 33-36**

New claims 33-36 have been added. Support for the limitations set forth in claims 33-36 can be found, *inter alia*, in FIGs. 5 and 8 of the Applicants' specification. These claims recite novel and non-obvious limitations. Moreover, claims 33-36 depend, either directly or by way of one or more intermediate claims, from claim 24 or claim 28. Accordingly, claims 33-36 are believed to be allowable over the prior art.

**VI. Conclusion**

Applicants respectfully request entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

Respectfully Submitted,  
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